

REMARKS

The instant Office Action mailed September 10, 2004, set a three-month shortened statutory period for response expiring December 10, 2004. This response is therefore timely filed.

The title has been amended in order to correct an obvious typographical error in the word “antipsychiotic” which now correctly reads as “antipsychotic.”

Claims 1-14 were in the application as originally filed. Claims 15-35 were added in the Preliminary Amendment filed on December 19, 2001. Claims 14 and 29-35 are cancelled without prejudice to the prosecution thereof in a continuing application. Claims 1-13 and 15-28 remain in the application.

Claims 1 and 2 have been amended to eliminate the non-elected subject matter of Groups II to VI therefrom. Applicants reserve the right to prosecute the deleted subject matter in a continuing application.

Claim 3 has been amended to insert the word “or” to correct an obvious typographical error. Support for this amendment can be found, for example, in claim 2, from which claim 3 depends.

Claims 9 to 11 have been amended to incorporate the compound of Formula (I) from base claim 1 directly into claims 9 to 11. Support for these amendments can be found, for example, on pages 8-10 of the specification.

Claims 13 and 22 to 28 have been amended to incorporate the limitations from cancelled dependent claims 14 and 29 to 35, respectively.

Claims 1, 2, and 9 to 35 are rejected as being drawn to an improper Markush group on the grounds that the recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents.

This rejection is believed overcome by the above-described amendments to claims 1 and 2, in which the non-elected subject matter has been deleted.

Claims 12, 13, and 15 to 28 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement for the stated reason that the specification, while being enabling for schizophrenia, does not reasonably provide enablement for all psychotic disorders. The Examiner maintains that there is no evidence to justify the contention that the claimed compounds can be useful in the treatment of “psychotic disorders.”

This rejection is traversed and reconsideration and withdrawal thereof is respectfully requested for the reasons given hereinbelow.

Without acquiescing in the propriety of the rejection, and solely to advance prosecution, applicants have amended claims 13 and 22 to 28 in order to particularly claim the methods of treating the positive and negative symptoms of schizophrenia, which the Examiner has acknowledged is enabled. Thus, the rejection of said claims under 35 U.S.C. § 112, first paragraph, is rendered moot.

Insofar as the instant rejection pertains to claims 12 and 15 to 21, applicants respectfully point out that the Examiner has failed to provide an explanation why the specification is considered non-enabling for the claimed pharmaceutical compositions, as the instant rejection focused solely on an alleged lack of enablement for treating psychotic disorders. Moreover, as stated in MPEP 2164.01(c):

[W]hen a compound or composition claim is not limited by a recited use, *any* enabled use that would reasonably correlate with the entire scope of *that* claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to *enable each disclosed use*. In other words, *if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention*. [emphasis added.]

The Examiner has acknowledged that the specification is enabling for schizophrenia. Since at least one disclosed use is enabled, then the application must be enabling for these composition claims, which are not limited by a specific use. Therefore, the rejection of claims 12 and 15 to 21 under 35 U.S.C. 112, first paragraph, is improper and reconsideration and withdrawal thereof is respectfully requested.

Claims 3-5, 9-11, 16-18, 23-25 and 30-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner bases this rejection on the following grounds:

- a) Claim 3 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R₁ which is not stated in a proper Markush form, i.e. there are two definitions for R₁.
- b) Claim 9 is vague and indefinite in that it is not known what is meant by (I) in the 2nd and 3rd lines from the bottom of page 4 and the 2nd, 4th, 13th, 17th, and 19th line of page 5 in the claim. There is no (I) in the claim.
- c) Claim 10 and claims dependent thereon are vague and indefinite in that it is not known what is meant by nascent hydrogen.

- d) Claim 10 is vague and indefinite in that it is not known what is meant by (I) in the 3rd, 4th, 6th, 7th, and 8th lines of page 6 in the claim. There is no (I) in the claim.
- e) Claim 11 is vague and indefinite in that it is not known what is meant by (I) in the 2nd line of the claim. There is no (I) in the claim.

This rejection is traversed and reconsideration and withdrawal thereof are respectfully requested for the reasons provided below, the individual rejections being addressed by the letters set forth by the Examiner.

- a) The rejection of claims 3-5, 16-18, 23-25, and 30-32 is believed overcome and should be withdrawn in view of the above-described amendment to claim 3, in which the word “or” was added before the alternative definition of R₁.
- b) The rejection of claim 9 with respect to the meaning of “(I)” is believed overcome and should be withdrawn in view of the above-described amendment to claim 9 in which the compound of claim 1, formula (I), was added directly into claim 9.
- c) With respect to the rejection of the phrase “nascent hydrogen” in claim 10, applicants would point out that the term “nascent” is a well-known term used in organic synthesis to refer to something newly generated, and in this case, would be recognized by one of skill in the art as indicating newly generated hydrogen to be utilized in the hydrogenation reaction set forth in claim 10. In this regard, applicants would refer the Examiner to page 1024 of the 25th edition of Stedman's Medical Dictionary (a copy of which is enclosed herewith for the Examiner's convenience) wherein the term nascent is defined as:
 - 1: Beginning; being born or produced
 - 2: Denoting the state of a chemical element at the moment it is set free from one of its compounds.

Accordingly, applicants submit that the instant process claim does indeed comply with the requirements of 35 U.S.C. §112, second paragraph, and that the rejection of claim 10 on this basis should, therefore, be withdrawn.

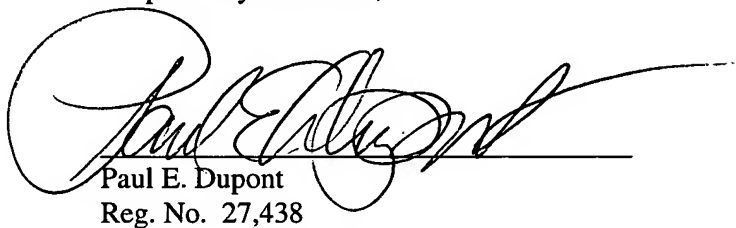
- d) The rejection of claim 10 with respect to the meaning of “(I)” is believed overcome and should be withdrawn in view of the above-described amendment to claim 10 in which the compound of claim 1, formula (I), was added directly into claim 10.

- e) The rejection of claim 11 with respect to the meaning of "(I)" is believed overcome and should be withdrawn in view of the above-described amendment to claim 11 in which the compound of claim 1, formula (I), was added directly into claim 11.

Claims 6 to 8 are deemed to be allowable but are objected to as being dependent upon rejected base claims. In view of the foregoing arguments, claims 1 to 5 are believed to be allowable, and, accordingly, claims 6 to 8 should be allowable in dependent form.

There being no remaining issues, this application is believed in condition for favourable reconsideration and allowance of Claims 1 to 13 and 15 to 28, and such action is earnestly solicited.

Respectfully submitted,



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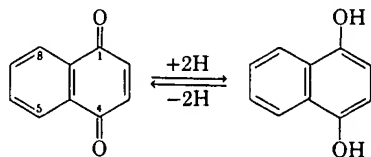
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thalene, reducible to naphthohydroquinone; 1,4-naphthoquinone derivatives have vitamin K activity *e.g.*, (menaquinone).



1,4-Naphthoquinone

naphthyl (naf'thil). The radical of naphthalene, $C_{10}H_7$.

α -naphthylthiourea (ANTU) (naf'thil-thi'ō-yū-rē'ā). 1-(1-Naphthyl)-2-thiourea; a derivative of thiourea; a highly toxic antithyroid agent, especially to small mammals, causing pulmonary edema, fatty degeneration of the liver, and low body temperature; used as a rat poison.

napier (nā'pē-er) [John Napier, Scottish mathematician, 1550–1617]. Neper.

naprapathy (nā-prap'ā-thē) [Bohemian *napravít*, to correct, + *G. pathos*, suffering]. A system of therapeutic manipulation based on the theory that morbid symptoms are dependent upon strained or contracted ligaments in the spine, thorax, or pelvis.

naproxen (nā-prok'sēn). (+)-6-Methoxy- α -methyl-2-naphthaleneacetic acid; an anti-inflammatory analgesic agent used in the treatment of rheumatoid conditions.

napsylate (nap'si-lāt). USAN-approved contraction for 2-naphthalenesulfonate.

Narath, Albert, Dutch surgeon, 1864–1924. See *N.'s operation*.

narceine (nar'sē-en). An alkaloid of opium; $C_{23}H_{27}NO_8$. Ethylnarceine is a narcotic, analgesic, and antitussive.

narcissism (nar-sis'izm, nar'si-sizm) [*Narkissos*, *G. myth. char.*]. 1. Self-love; autosexualism (2); autophilia; sexual attraction toward one's own person. 2. A state in which the individual regards everything in relation to himself and not to other persons or things. **primary n.**, in psychoanalysis, the original psychic energy embodied or invested in the ego.

secondary n., in psychoanalysis, the psychic energy once attached to external objects, but now withdrawn from those objects and reinvested in the ego.

narco- [*G. narkoun*, to benumb, deaden]. Combining form relating to stupor or narcosis.

narcoanalysis (nar'kō-ā-nal'i-sis). Narcosynthesis; psychotherapeutic treatment under light anesthesia, originally used in acute combat cases during World War II. See also *narcotherapy*.

narcohypnia (nar'kō-hip'nē-ā) [*narco-* + *G. hypnos*, sleep]. A general numbness sometimes experienced at the moment of waking.

narcohypnosis (nar'kō-hip-nō'sis) [*narco-* + *G. hypnos*, sleep]. Stupor or deep sleep induced by hypnosis.

narcolepsy (nar'kō-lep-sē) [*narco-* + *G. lépsis*, seizure]. Paroxysmal sleep; hypnolepsy; Friedmann's disease; Gélineau's syndrome; a sudden uncontrollable disposition to sleep occurring at irregular intervals, with or without obvious predisposing or exciting cause, usually involving an abnormality in sleep-stage sequencing.

narcosis (nar'kō'sis) [*G. a benumbing*]. General and nonspecific reversible depression of neuronal excitability, produced by a number of physical and chemical agents, usually resulting in stupor rather than in anesthesia (with which *n.* was once synonymous).

nitrogen n., (1) *n.* produced by nitrogenous materials such as occurs in certain forms of uremia and hepatic coma; (2) the stuporous condition characterized by disorientation and by loss of judgment and skill, attributed to an increased pressure of nitrogen as occurs with divers breathing air during underwater operations. Commonly referred to as "rapture of the deep."

narcosynthesis (nar'kō-sin'thē-sis). Narcoanalysis.

narcotherapy (nar'kō-thār'ā-pē). Psychotherapy conducted with the patient under the influence of a sedative or narcotic.

narcotic (nar-kot'ik) [*G. narkōtikos*, benumbing]. 1. Any substance producing stupor associated with analgesia. 2. Specifically, a drug derived from opium or opium-like compounds, with potent analgesic effects associated with significant alteration of mood and behavior, and with the potential for dependence and tolerance following repeated administration. 3. Capable of inducing a state of stuporous analgesia.

dl-narcotine (nar'kō-tēn). Gnoscapine.

l- α -narcotine. Noscapine.

narcotism (nar'kō-tizm). 1. Stuporous analgesia induced by a narcotic. 2. Addiction to a narcotic.

naris, pl. **nares** (nā'ris, -rē-ūm, -res) [*L.*] [*NA*]. Nostril; prenasal; anterior opening on either side of the nasal cavity.

anterior n., *n.*

posterior n., choana.

nasal (nā'zāl) [*L. nasus*, nose]. Rhinal; relating to the nose.

nascent (nas'ent, nā'sent) [*L. nascor*, pres. p. *nascens*, to be born].

1. Beginning; being born or produced. 2. Denoting the state of a chemical element at the moment it is set free from one of its compounds.

nasioinial (nā'zē-ō-in'ē-ak). Relating to the nasion and inion; denoting the distance in a straight line between the frontonasal suture and the external occipital protuberance.

nasion (nā'zē-on) [*L. nasus*, nose] [*NA*]. Nasal point; a point on the skull corresponding to the middle of the nasofrontal suture.

Nasmyth, Alexander, London dentist, †1847. See *N.'s cuticle membrane*.

naso- [*L. nasus*, nose]. Combining form relating to the nose.

nasooantral (nā'zō-an'trāl). Relating to the nose and the maxillary sinus.

nasociliary (nā'zō-sil'ē-ār-ē). See *nervus nasociliaris*.

nasofrontal (nā'zō-frūn'tāl). Relating to the nose and forehead, or to the nasal cavity and frontal sinuses.

nasogastric (nā'zō-gas'trik). Pertaining to or involving the nasal passages and the stomach, as in *n. intubation*.

nasolabial (nā'zō-lā'bē-āl) [*naso-* + *G. labium*, lip]. Relating to the nose and upper lip.

nasolacrimal (nā'zō-lak'ri-māl). Relating to the nasal and the lacrimal bones, or to the nasal cavity and the lacrimal ducts.

naso-oral (nā'zō-ō'rāl). Relating to the nose and mouth.

nasopalatine (nā'zō-pal'ā-tēn, -tin). Relating to the nose and the palate.

nasopharyngeal (nā'zō-fā-rin'jē-āl). Rhinopharyngeal. (1)

1. Relating to the nose or nasal cavity and the pharynx. 2. *Pars nasalis pharyngis*.

nasopharyngitis (nā'zō-far-in-jī'tis). Rhinopharyngitis.

nasopharyngolaryngoscope (nā'zō-fa-ring'gō-lā-ring'gō-skōp). An instrument, often of fiberoptic type, used to visualize the upper airways and pharynx.

nasopharyngoscope (nā'zō-fa-ring'gō-skōp). Telescopic instrument, electrically lighted, for examination of the nasal passages and the nasopharynx.

nasopharyngoscopy (nā'zō-fa-ring-gos'kō-pē) [*nasopharynx* + *G. skopeō*, to view]. Examination of the nasopharynx by flexible or rigid optical instruments, or with a mirror.

nasopharynx (nā'zō-far'ingks). *Pars nasalis pharyngis*.

nasorostral (nā'zō-ros'trāl). Relating to the nasal cavity and the rostrum of the sphenoid bone.

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